Refine Search

Search Results -

Term	Documents
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WATERS	47122
FATTY	152980
FATTIES	0
FATTYS	2
ACID	695633
ACIDS	396312
ETHANOL	252516
ETHANOLS	1858
PROPYLENE	208885
PROPYLENES	393
(L1 AND WATER AND FATTY ACID AND (ETHANOL OR PROPYLENE GLYCOL)).USPT.	249

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US OCR Full-Text Database
EPO Abstracts Database
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IBM Technical Disclosure Bulletins

Search: L3

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Recall Text Clear Interrupt

Search History

DATE: Thursday, August 10, 2006 Printable Copy Create Case

Set Name side by side	Query	Hit Count	Set Name result set
	DB=USPT; PLUR=YES; OP=ADJ		

L3	l1 and water and fatty acid and (ethanol or propylene glycol)	249	L3
L2	l1 same water same fatty acid	1	L2
L1	Ritonavir or norvir	777	L1

END OF SEARCH HISTORY

Hit List

First Hit | Clear | Generate Collection | Print | Fwd Refs | Bkwd Refs | Generate OACS

Search Results - Record(s) 1 through 1 of 1 returned.

☐ 1. Document ID: US 6797283 B1

L2: Entry 1 of 1 File: USPT Sep 28, 2004

US-PAT-NO: 6797283
DOCUMENT-IDENTIFIER: US 6797283 B1

TITLE: Gastric retention dosage form having multiple layers

L2: Entry 1 of 1 File: USPT Sep 28, 2004

DOCUMENT-IDENTIFIER: US 6797283 B1
TITLE: Gastric retention dosage form having multiple layers

Detailed Description Text (123):
The present invention is described and characterized by one or more of the following technical features and/or characteristics, either alone or in combination with one or more of the other features and characteristics: an active agent dosage form adapted for gastric retention comprising: (a) a first layer comprising a swellable, water-soluble polymer; (b) a second layer comprising a therapeutically-effective amount of an active agent, the second layer being laminated with the first layer at a common surface, and (c) at least one band of insoluble material circumscribing and binding together the first layer and the second layer, the first layer being adapted to swell in the stomach to facilitate retention of the dosage form in the stomach over a prolonged period of time, wherein the release of the active agent from the second layer is independent of the composition of the first layer and occurs over a prolonged period of time; a dosage form wherein the number average molecular weight of the water-soluble polymer is between about 100,000 and 20,000,000 grams per mole; a dosage form wherein the water soluble polymer is polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose, calcium carboxymethyi cellulose, methyl cellulose, polyacrylic acid, maltodextrin, pre-gelatinized starch, guar gum, sodium alginate, or polyvinyl alcohol; a dosage form wherein the second layer comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked Amberlite resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules and sodium carboxymethyl starch, and the first layer optionally comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked Amberlite resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules and sodium carboxymethyl starch; a dosage form wherein the first layer swells more rapidly and to a greater extent than does the second layer; a dosage form wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic,

hypoglycemic, antidepressant, antiobesity or antifungal active agent; a dosage form wherein the weight percent of the water soluble polymer in the second layer is 5 to 99.99 weight percent and weight percent of the hydroattractant in the second layer is 0 to 60 weight percent; a dosage form wherein the prolonged time period is at least 3 hours; a dosage form wherein the prolonged time period is between about 6 to 12 hours; a dosage form wherein the first layer comprises polyethylene oxide having a number average molecular weight of at least 100,000 grams per mole; a dosage form wherein the active agent is acyclovir, ganciclovir, ritonavir, minocycline, cimetidine, ranitidine, captopril, methyldopa, selegiline, minocycline, fexofenadine, metformin, bupropion, orlistat or a pharmaceutically acceptable salt thereof; a dosage form wherein the second layer comprises an active agent selected from the group consisting of acyclovir, ganciclovir, ritonavir, metformin, bupropion, orlistat and minocycline, and the second layer comprises a bioerodible polymer, a therapeutically effective amount of the active agent being delivered to the stomach of a subject over at least a 3 hour period; a method of treating a subject in need thereof with an active agent that comprises administering to the subject a multilayered dosage form adapted to be retained in the stomach over a prolonged period of time, the dosage form comprising a second layer adapted to swell in the stomach of the subject and retain the dosage form in the stomach for a prolonged period of time, and a first layer adapted to deliver to the subject an active agent at a variable rate of delivery; a method which comprises administering one or more dosage forms to the subject in the fed state at the start of each dosing period; a method wherein the administration of the dosage form occurs within one hour of the subject consuming food; a dosage form comprising a gastric-emptying delaying agent; a dosage form wherein the gastric-emptying delaying agent is selected from anticholinergic agents, methylcellulose, guar gum, fats and fatty acids of 10-15 carbon atoms; a dosage form wherein the active agent comprises a liquid, active agent formulation; a dosage form wherein the liquid, active agent formulation is sorbed into porous particles; a dosage form wherein the porous particles are calcium hydrogen phosphate or magnesium aluminometasilicate; a dosage form comprising a pH regulating agent or a chelating agent; a dosage form wherein the liquid, active agent formulation comprises a pH regulating agent selected from organic and inorganic acids and bases, a dosage form wherein the liquid, active agent formulation comprises a chelating agent.

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Previous Page Next Page Go to Doc#